TECHNOLOGY OVERVIEW

Syringe Safety Controls

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Accidental syringe needlesticks to healthcare workers and others is a pervasive problem that has received considerable attention from government, professional organizations, and device manufacturers. The introduction of new devices has been supported by government requirements for the use of "engineered" sharps protection. The legislation has resulted in a wide variety of technical approaches, but with inadequate determination of the relative merits of the various devices. Despite the attention being paid to preventing syringe needlesticks, they continue to be a significant problem that requires further attention to safety and safety effectiveness.

The risk that healthcare workers (HCWs) take everyday when using syringe needles is much greater than most people probably think. Although the number of HCWs that experience seroconversion of a disease obtained through an accidental needlestick is low compared to the number of syringes used each year, the result to those infected is devastating, and the cost of treatment is very high. Beyond actual infection, the stress of being stuck is considerable, as is the cost of determining if there has been an infection. To address the danger of accidental needlesticks, numerous manufacturers have developed "safety-engineered" syringes with automatic or manual mechanisms to eliminate or cover the needle after use. Yet accidental needlesticks continue for HCWs with a high total number of incidents. In addition to HCWs, used needles can be hazardous to patients, family, and incidental contact with others, including occupational hazards to emergency, law enforcement, corrections, waste management, and custodial workers.[1] It is known that most needlesticks are associated with the means of use of the device, rather than device failure, although there are some reports of the latter.

Critical questions in addressing the ongoing incident rate are: Why are these safety device syringes not being more widely used, or if used, not being more effective? Are all of the available devices equally effective? If the best of these syringes are preferentially used, will the incident rate be lowered? Is the reason for the accidental needlestick simply carelessness on the part of the HCW, or is it a fundamental example of inadequate human factors engineering of the protective equipment?

Background

The 3 main infected needle diseases that are of primary concern are Hepatitis B, Hepatitis C, and AIDS. Other blood-borne diseases and infections can also occur such as Diphtheria, Typhus, Herpes, Malaria, Tuberculosis, Spotted Fever, Syphilis, and Gonorrhea, but these are less often reported and less studied.[2] Most healthcare centers routinely treat workers with drugs to prevent seroconversion after they have reported being stuck. It is therefore the needlestick incident itself that generates a large portion of the cost even if there is no resultant disease. Although the likelihood of transmission from one needlestick is low, the drug cost ranges from $500 to $3000. The emotional cost is also substantial, including the fear or anxiety of contracting a possibly fatal disease.[3] The total number of needlesticks is staggering. The Centers for Disease Control (CDC) estimates that 385,000 needlestick injuries and other related sharps injuries are sustained by hospital and other medical workers each year,[3] whereas another study estimates that 600,000 to 800,000 needlesticks occur each year.[4] Multiplying this estimate by the cost of follow-up treatment results is a very large price to pay for accidents that might have been prevented. Moreover, some victims of needlesticks are seriously affected and even die as a result.

Organizations Focused on Prevention

There are various private and public organizations that address the problem of accidental needlesticks. The Food and Drug Administration (FDA) has responsibility for the assurance of safety and effectiveness of medical devices being marketed and for collecting device experience data under the Medical Device Reporting requirements. The Occupational Safety and Health Administration (OSHA) sets workplace requirements for blood-borne hazards and the National Institute of Occupational Safety and Health (NIOSH), within the federal CDC, has issued guidelines and prevention strategies for HCWs. Another organization, the International Sharps Injury Prevention Society (ISIPS), is a diverse organization "formed to reduce the number of accidental sharps injuries that occur globally by promoting the use of safety-engineered products."[1] Yet another organization, the National Alliance for the Primary

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Prevention of Sharps Injuries (NAPPSI), has provided recommendations and notifications to HCWs regarding accidental needlesticks,[5] whereas EpiNet[6] has an educational and data collection program. Nursing and infection control organizations also have active and ongoing educational efforts, and numerous general guidelines have been published. The presence of these multiple organizations and publications illustrates both the severity of the problem facing HCWs, and the fractured nature of the governmental and private effort to bring about effective prevention.

The critical question is "How and why are healthcare workers getting stuck with used needles?" Most healthcare workers have extensive training with needles and are typically in-serviced when new needle products are introduced, proving that it is not a lack of procedural knowledge that results in a needlestick. It is also not likely to be simple carelessness, given the nature of the risk and the skill level of the affected personnel. What is more likely is that, at least for some of the devices, their required procedures are inconsistent with the reality of the environment and other conditions of actual use. Moreover, some of these devices may actually be inherently dangerous themselves, especially those requiring 2 hands, or unrealistic dexterity with 1 hand.

Many studies have been conducted by various organizations to determine why healthcare workers are accidentally stuck. One study conducted by the National Surveillance System for Healthcare Workers (NaSH) reported that 40% of injuries occurred during inpatient procedures and 25% occur in the operating room. Nurses sustain 44% of the injuries, with doctors coming in second highest at 28%.[3] Not all of the statistics pertain to syringe accidents because the numbers cited here are for harmful exposure to bodily fluid. However, this broader category does include accidental needlesticks. A more pertinent study by NaSH reported the following data[3] (Figure 1).

The 2 main categories that the data include are the process of disposal and procedural handling of the needle. Although there are a number of other such studies, the reported data in all these studies are noticeably lacking in information on exactly what product was being used by the stuck worker. This fact is surprising and unfortunate because OSHA and some states require that this information be collected by hospitals, and other organizations (eg, CDC and EpiNet[6]) also collect it. The lack of reporting of this information adds to the challenge of selecting the most effective preventative products, and sharing information about what works and what does not. The lack of device-specific data may also leave particularly ineffective and/or dangerous products in the marketplace with a concomitant false sense of security.

An obvious fact that may be overlooked when analyzing the problem is that from a disease transmission perspective the needle just needs to be protected *after* it has been used in a patient. Although needlesticks can occur before use, the consequences are minor compared to accidents after injections. However, even here, if the stick is with a clean needle, that needle now can present a biohazard until properly secured. In this regard, it may be the case that the stuck HCW is not highly motivated to secure the needle that just stuck them, as their concern turns to their own injury. If the needle can be rendered harmless instantly and easily after use, the problem of postuse incidents would be substantially lessened, if not eliminated.

What is there to fix the problem? The ideal solution might appear to be to eliminate needles, but needle-less solutions introduce other environmental factors such as possible infectious sources to the patient. They can also present considerable cost challenges and are not suitable for a wide range of medical needs. Needle-less systems are sometimes used in less developed countries, but more often conventional needles are reused because of cost and supply. Here inadequate sterilization has been a major cause of worldwide needle transmitted infection.

Safety Features

When evaluating effectiveness of use, there are many factors to be considered. The design of an effective safety

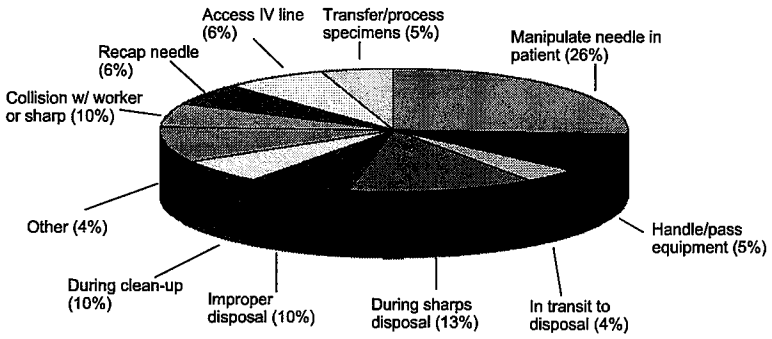

FIGURE 1. *NaSH data regarding causes of needle injuries.*[3]

syringe should require minimal additional training, be consistent in handling to the original syringe, be a simple 1-handed operation to avoid risk to the other hand (even if the other hand is not otherwise engaged), provide a clear indication of the safety feature's activation, and have needle-protective results that are irreversible or tamper-proof. The safety-engineered controls currently available on syringes can be divided into 2 categories: passive and active.[7] Passive controls are "in effect before, during, and after" the procedure. They are automatic, thus not requiring any additional training or effort on part of the HCW. The other controls are active, requiring manual activation by the HCW. The majority of today's safety-engineered controls for syringes are in the active category. However, as with most categorizations, this distinction is not totally clear, and not all devices within a category perform in an equal or equivalent manner.

Within the active category, there are many types of needle safety guards, manufactured by various companies. Although they are all manually operated to cover or remove the needle, they differ substantially in the means to achieve this outcome. The primary prevention categories include sliding sheath needle guards, hinged recapping needle guards, retractable needles, and prefilled syringes.[5]

The sliding sheath needle guards are the most numerous and varied products available. When consistently and correctly used, the sheath reduces the possibility of being stuck after use on the patient. The basic design of any sheath is a sliding protector placed on the syringe that is manually activated by pushing the sheath up over the needle. In many cases, the sheath has a locking mechanism or color-coded indicator that the needle is completely covered. Some of these syringes allow for the plunger to be broken away from the needle and the sheath. Depending upon the manufacturer and the device, sliding sheath needle guards can present a challenge for realistic 1-handed use, and in some cases, the needle is not so deep in the sheath that the point is beyond contact by inadvertently (or deliberately) inserting a finger into the sheath barrel. In most cases, these integral sheath designs are add-on modifications to traditional syringes. Some sheaths, however, are accessory products that are sold separately from the standard syringe. One example of a sliding sheath needle guard is the Gettig Guard Safety Needle.[8] The Gettig Guard sheath is said to fit any standard syringe. It requires push-button activation to cover the needle. The activation implies a 2-stage training process, the first being to routinely acquire and add the guard product to the separate syringe, and the second to activate it correctly. Also, the lock-activation is a push-button which does not give a clear indication of when it is locked, thus not assuring that the results are irreversible. However, the Gettig Guard when installed correctly is a 1-handed operation. The Becton Dickinson Safety-Lok Syringe is another sliding sheath syringe which claims to prevent accidental needlesticks.[9] According to the directions for the Safety-Lok Syringe, it requires minimal training, is consistent to the handling of the original syringe, provides a clear indication of the safety features activation, and its results are irreversible. However, it requires 2 hands to activate, providing an increased risk of a stick to the other hand during use. Similarly, the DuoProSS™-Retractable Safety Syringe provides a locking mechanism by pulling the plunger back after injection and then breaking the plunger off.[10] Unfortunately, the activation of this safety mechanism appears to be 2-handed. In fact, many safety-syringe manufacturers will advertise the syringe as a 1-handed operation, when, in reality, 2 hands are either required to activate the mechanism efficiently or 2 hands are likely to be used even if it is theoretically possible, with sufficient dexterity, to do it with 1 hand.

Hinged recapping guards are protective coverings on syringes that can be activated with 1 hand to cover the needle, if the user can get that one hand into the capping position up on the barrel without using the other hand, which is another dexterity challenge. The guard is typically pressed forward at a hinge until the sheath slides up and "locks" around the needle. However, the HCW's finger moves toward the needle tip while pushing the hinge forward, increasing the risk of an accidental stick. It is also possible that the bulk of the hinged cap is an interference or an annoyance during normal use of the syringe. In some cases, it has been reported that the un-deployed cap can also act as an inadvertent lever that can unscrew the needle from the syringe body. The locking mechanism on this type of device can be easily reversed by an unauthorized user, for example. The BD Safety Glide Shielding Hypodermic Needle is an example of the hinged recapping guard.[9]

The third, and most effective, protection device is the retractable needle. Retractable Technology's Vanishpoint syringe retracts into the barrel after the injection has been administered and a final push is applied to the plunger with the using hand in the same position.[11] Other manufacturers, such as Safety First Medical Incorporated,[12] require the HCW to press a button to retract the needle. Operation of the SecureGard syringe requires the HCW to pull the plunger back after the injection has been administered to retract the needle into the syringe barrel.[13] The additional step of pulling the plunger back requires an at best difficult 1-handed operation or more likely a 2-handed operation, with the latter adding potential exposure of the second hand.

Human Factors

Realistically expected and actually observed use versus the theoretical possibility of safe and effective use is a core issue in human factors and the prevention of use error. Reliance on training the user to consistently perform a protective act that is difficult and nonintuitive is a false reliance in that such training can be predicted to be ineffective. Subsequently, blaming the user for their failure

is equally pointless and counterproductive. Only designs that address real user needs and probable behavior can be expected to actually be effective.

Conclusion

The various "safety-engineered" controls for syringes and the numerous organizations dedicated to preventing accidental needlesticks are proof that the healthcare industry has a severe problem. Although many alternatives to normal syringes exist, they are not equally well designed, and therefore, not equally safe. In this regard, it should be noted that product names incorporating safe, safety, and secure, as well as catchy and deliberate misspellings of these terms, have not necessarily been shown to actually achieve these attributes. Furthermore, devices that are not likely to actually be used effectively cannot significantly reduce risk, and even the best products cannot reduce risk if they are not implemented into the everyday workplace. With the legislation that is currently signed into law and organizations active in the government and private sector, hopefully, more healthcare centers will take real and effective action to protect their workers and invest in syringe safety devices that really help to prevent accidents.

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